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Attorney Docket No. 18608-002410US

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Date of Deposit: November 21, 2000

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By: _____
Jason Negrette

ASSISTANT COMMISSIONER FOR PATENTS
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Sir:
Transmitted herewith for filing under 37 CFR 1.53(b) is the
[X] patent application of
[ ] continuation patent application of
[ ] divisional patent application of
[ ] continuation-in-part patent application of

Inventor(s)/Applicant Identifier: DAVID G. MATSUURA et al.

For: BONE GRAFT HARVESTER

[X] This application claims priority from each of the following Application Nos./filing dates:
60/167,192 filed November 23, 1999, the disclosure(s) of which is (are) incorporated by reference.

Enclosed are:
[X] 9 total page(s) of specification
[X] 3 page(s) of claims
[X] 1 page of Abstract
[X] 20 sheet(s) of [ ] formal [X] informal drawing(s).
[X] A [ ] signed [X] unsigned Declaration.
[X] Limited Recognition Form
[X] Return Postcard

In view of the Unsigned Declaration as filed with this application and pursuant to 37 CFR §1.53(f), Applicant requests deferral of the filing fee until submission of the Missing Parts of Application.

DO NOT CHARGE THE FILING FEE AT THIS TIME.

David Heckadon
(Granted Limited Recognition under 37 CFR §10.9(b) – see enclosed Limited Recognition Document)
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PA 3111543 v1

Attorney Docket No.: 18608-002410

PATENT APPLICATION

BONE GRAFT HARVESTER

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BONE GRAFT HARVESTER

CROSS-REFERENCES TO RELATED APPLICATIONS

This application claims the benefit of prior provisional application no. 60/167,192 filed November 23, 1999, the full disclosure of which is incorporated herein by reference.

The present invention relates to systems for removing bone graft material from a patient, and in particular to systems for removing bone graft material from a patient's ilium.

SUMMARY OF THE INVENTION

The present invention provides a bone graft harvesting drill comprised of a flexible tubular member having a hollow cylindrical drill bit mounted at its distal end. An advantage of the present harvesting drill is that it can be used to remove softer cancellous bone from between the harder cortical plates of the patient's ilium. Specifically, the present harvesting drill can be advanced in a path between the plates of the ilium, with the drill automatically tending to deflect off the hard cortical surfaces of the bone such that the drill instead bores a path therebetween through the cancellous bone material.

In preferred aspects, the drill bit has a plurality of wavy or sinusoidal teeth which may be sharpened such that the outer surfaces of the teeth taper inwardly towards their distal ends, wherein the inner surfaces of the teeth are aligned with the walls of the drill bit. An advantage of sharpening the teeth such that their outer surfaces slant inwardly while their inner surfaces remain parallel is that as the outer surface of the distal tip of the drill bit comes into contact with the curved inner surface of the cortical plate of the patient's ilium, the bevel or chamfer at the distal tip causes the distal tip to deflect away from the cortical bone. As the main body of the drill is flexible in radial directions, (i.e.: perpendicular to a longitudinally extending axis passing therethrough), and is preferably relatively rigid in compression along the longitudinal axis of the drill, a transverse load on the beveled end of the drill bit results in a "passive steering" condition. This "passive steering" feature of the device allows the harvesting drill to take the desired path of least resistance through the softer cancellous bone while preserving the harder cortical bone. Should the outermost edges of the drill tip instead be sharp, and not beveled or chamfered, the drill bit may instead have a tendency to catch the inner surface of the

cortical bone and would undesirable pass through the ilium into the surrounding tissue. Another advantage of the beveled tip is that it is easier to push the drill through the bone during cutting.

In preferred aspects, an optional tissue removing insert is slidably received through the inner bores of the flexible tubular member and the drill bit. This tissue removing insert is specifically adapted to anchor into and, when rotated, tear away tissues which have become disposed within the inner bore of the drill bit.

In further optional aspects of the present invention, inwardly facing projections are found on the drill bit. These projections are specifically adapted to tear away tissues which have become disposed within the inner bore of the drill bit. In preferred aspects, the inwardly facing projection is formed from a C-shaped or L-shaped cut through the wall of the drill bit wherein the inner flange is bent inwardly into the bore of the drill bit. In alternate preferred aspects, a blade spans across the bore of the drill bit to tear away tissues protruding therein. An advantage of this embodiment of the invention is that the blade acts as a morcillator to pre-masticate the tissue prior to placement into the patient.

In a preferred method of using the present invention, the flexible tube and attached drill bit are rotated, however, they may instead be oscillated such that they preferentially cut through the softer cancellous tissues, avoiding harder cortical tissues.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of the present invention.

Fig. 2 is a close-up of the distal end of the present invention.

Fig. 3 is a sectional view of the distal end of the present invention.

Fig. 4 is a sectional view of the distal end of the present invention showing in the present invention cutting into a bone.

Fig. 5 corresponds to Fig. 4, but shows a tissue removing insert anchored into a tissue mass protruding into the inner bore of the present invention.

Fig. 6 shows removal of the tissue mass from the inner bore of the invention.

Fig. 7 is a side elevation view of an embodiment of the invention having an inwardly facing projection in the drill bit.

Fig. 8 is a view corresponding to line 8-8 in Fig. 7.

Fig. 9 is similar to Fig. 7, but shows the inwardly facing projection disposed at an angle.

Fig. 10 shows an embodiment of the distal end of the present invention having a blade spanning across the inner bore of the drill bit.

Fig. 11 is a front view corresponding to Fig. 10.

Fig. 12 is a view taken along line 12-12 in Fig. 11.

Fig. 13 is a view taken along line 13-13 in Fig. 11.

Fig. 14 is an illustration of the direction of travel of the present invention as it moves between the tables of the ilium.

Fig. 15 is a side elevation view of the present invention.

Fig. 16 is a sectional view corresponding to line 16-16 in Fig. 15.

Fig. 17 is a side elevation view of the distal tip of the present invention.

Fig. 18 is a sectional view corresponding to line 18 in Fig. 17.

Fig. 19 is a side elevation view of the present invention.

Fig. 20 is a sectional view corresponding to line 20-20 in Fig. 19.

Fig. 21 is a side elevation view corresponding to Figs. 19 and 20.

Fig. 22 is a schematic view of the present drill positioned between the tables of the ilium.

Fig. 23 is a close-up view of corresponding to Fig. 22.

Fig. 24 is a close-up view of corresponding to Fig. 23.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Referring to Fig. 1, the present invention comprises a bone graft harvesting drill 10 comprised of a flexible tubular member 12 with a hollow cylindrical drill bit 14 mounted to the distal end of the flexible tubular member 12 as shown. Preferably, the tubular member 12 is made from a biocompatable thermoplastic such as polyethylene or polypropylene, however, many other plastics could be used.

The drill bit 14 is preferably made from stainless steel, however, other materials could be used, such as hard metals or hard thermoplastics.

As can be seen in Fig. 2, drill bit 14 has a plurality of teeth 16 which wrap around its circumference. Preferably, teeth 16 are “wavy” or sinusoidal in shape as shown. An advantage of such a serrated tooth is that it is non-clogging, as opposed to a typical triangular saw tooth, which has a tendency to catch materials in the spaces between the teeth. A further advantage is that the aggressiveness of the tip of the drill is

more easily controlled in the serrated type tip than in more conventional saw tooth forms. If the bit becomes too aggressive, damage to the inner planes of the cortical bone may occur. Furthermore, the serrated type tip is much easier and more cost effective to manufacture than conventional saw tooth forms.

Referring to Fig. 3, a sectional view of drill 10 is shown. Teeth 16 have outer surfaces 15 and inner surfaces 17. In a preferred aspect, inner surfaces 17 taper outwardly towards the distal end of drill 10. Inner surfaces 15 are preferably aligned parallel with one another and parallel with the outer surface of drill bit 14 as shown. An advantage of having outer surfaces 17 taper inwardly (as opposed to having inner surfaces 15 tapered outwardly), is that the drill bit 14 can be advanced to cut into tissues more easily.

Fig. 4 shows drill 10 cutting into bone B. In a preferred aspect of the invention, drill 10 is rotated, about a central longitudinal axis A extending therethrough.

As seen in Fig. 4, a mass of bone tissue B1 will enter into the central bore of drill 10 as drill 10 is cut into the bone. In an optional preferred aspect of the present invention, a tissue removing insert 20 is introduced into the central bore of drill 10 as shown in Fig. 5. Insert 20 may comprise a screw-type mechanism as illustrated, or any other system for gripping into and tearing away tissue mass B1. As seen in Fig. 6, insert 20 is used to tear away and remove tissue mass B1 from the inner bore of drill 10, such that tissue mass B1 can be used as bone graft material. The sequence of steps illustrated in Figs. 4, 5, and 6 can preferably be repeated again and again as drill 10 advances further and further into bone B.

An additional preferred aspect of the invention is illustrated in Fig. 7 and 8 in which an inwardly facing projection 25 which may be formed by a C-shaped cut 26 in drill bit 14 is found. Specifically, as seen in Fig. 8, projection 25 is bent to face inwardly into the inner bore of drill 10. An advantage of the projections 25 facing inwardly are that as drill 10 is advanced, projections 25 will tend to tear away tissue protruding therein such that the tissue can easily be removed from the central bore of drill such that it can be used for bone graft purposes. In preferred aspects, a plurality of projections 25 can be disposed around the circumference of drill bit 14. Preferably, such inwardly facing projections 25 will be disposed equidistantly around the circumference of drill bit 14. In preferred aspects, two, three, four or more of inwardly facing projections 25 may be used.

Fig. 9 shows an inwardly facing projection 27 formed by a C-shaped cut 29 wherein projection 27 is disposed at an angle to axis A. An advantage of

projection 27 being angled to axis A is that it will tend to screw into the tissue mass disposed within the inner bore of drill 10, such that the tissue mass can be more easily torn away and removed.

Fig. 10 shows an alternate embodiment of the present invention in which a blade 30 spans across the bore of drill bit 14 as shown. As can be seen more clearly in Figs. 11, 12, and 13, blade 30 may comprise two sections 32 and 34 which may be oppositely angled such that as drill 10 is rotated, each of blades 32 and 34 cut into the tissue which becomes disposed within the inner bore of drill bit 14 such that the tissue can be easily removed from the inner bore of drill bit 14.

Figs. 14 and 22 to 24 show a preferred direction of travel for drill 10 wherein drill 10 is introduced into ilium 40 into a region of cancellous bone 42 disposed between ilium tables 44 and 46. Tables 44 and 46 comprise a very hard cortical bone. As such, as drill 10 is advanced in a distal direction, drill bit 14 will tend to be deflected along table 46 such that it cuts through cancellous bone 42, without cutting through either of tables 44 or 46. This is achieved by tube 12 being flexible such that it is able to respond to deflections of movement of drill bit 14 as drill 10 travels along path P as shown.

Bending of flexible tubular member 12 is also shown in Figs. 20 and 21.

WHAT IS CLAIMED IS:

1. A bone graft harvesting drill, comprising:

a flexible tubular member; and

a hollow cylindrical drill bit mounted to a distal end of the flexible tubular member.

2. The bone graft harvesting drill of claim 1, wherein the flexible tubular member is made from semi-rigid thermoplastic.

3. The bone graft harvesting drill of claim 1, wherein the drill bit has a plurality of serrated teeth.

4. The bone graft harvesting drill of claim 1, wherein the drill bit has a plurality of teeth having inner and outer surfaces, wherein the outer surfaces of the teeth taper inwardly towards their distal ends, and wherein the inner surfaces of the teeth are aligned with the outer surface of the hollow cylindrical drill bit.

5. The bone graft harvesting drill of claim 1, further comprising:

a tissue removing insert received within the inner bores of the flexible tubular member and the drill bit, the tissue removing insert being adapted to tear away tissues disposed within the inner bore of the drill bit.

6. The bone graft harvesting drill of claim 5, wherein the tissue removing insert is adapted to be slidably positioned within the inner bores of the flexible tubular member and the drill bit.

7. The bone graft harvesting drill of claim 1, wherein the drill bit comprises:

at least one projection facing inwardly into the bore of the drill bit, the projection being adapted to tear away tissues disposed within the inner bore of the drill bit.

8. The bone graft harvesting drill of claim 7, wherein,

the at least one projection comprises a plurality of inwardly facing projections disposed equidistantly around the circumference of the drill bit.

9. The bone graft harvesting drill of claim 7, wherein,

the at least one projection is formed from a C-shaped or L-shaped cut passing through the wall of the drill bit.

10. The bone graft harvesting drill of claim 7, wherein,

the at least one projection comprises a blade spanning across the bore of the drill bit.

11. A method of harvesting bone graft material, comprising:

inserting a distal end of a hollow cylindrical drill into a patient's ilium, the distal end of a hollow cylindrical drill comprising a flexible tubular member, with a hollow cylindrical drill bit mounted to the distal end of the flexible tubular member; and

rotating or oscillating the flexible tubular member about a longitudinal axis extending therethrough; and,

advancing the hollow cylindrical drill such that cut away tissue is deposited in the inner bore of the hollow cylindrical drill.

12. The method of claim 11, wherein the hollow cylindrical drill is advanced such that the distal end of the cylindrical drill bit deflects off an inner boundary of the outer surface of the ilium, thereby cutting the cancellous bone while avoiding cutting cortical bone.

13. The method of claim 11, further comprising:

slidably inserting a tissue removal insert into the inner bores of the flexible tubular member and cylindrical drill bit;

anchoring the tissue removal insert into a mass of tissue protruding into the bore of the cylindrical drill bit;

tearing away the mass of tissue by rotating the tissue removal insert; and

removing the mass of tissue from within the bore of the cylindrical drill bit by slidably removing the tissue removal insert from the inner bore of the cylindrical drill bit.

14. The method of claim 11, further comprising:

tearing away a mass of tissue protruding into the bore of the cylindrical drill bit with a protrusion which faces inwardly from an inner wall of the cylindrical drill bit into the bore of the cylindrical drill bit.

15. The method of claim 11, further comprising:

tearing away a mass of tissue protruding into the bore of the cylindrical drill bit with a blade spanning across the bore of the drill bit.

16. The method of claim 11, wherein the hollow cylindrical drill is inserted in a percutaneous cannulated approach.

BONE GRAFT HARVESTER

ABSTRACT OF THE DISCLOSURE

A bone graft harvesting drill, comprising: a flexible tubular member and a hollow cylindrical drill bit mounted to a distal end of the flexible tubular member.

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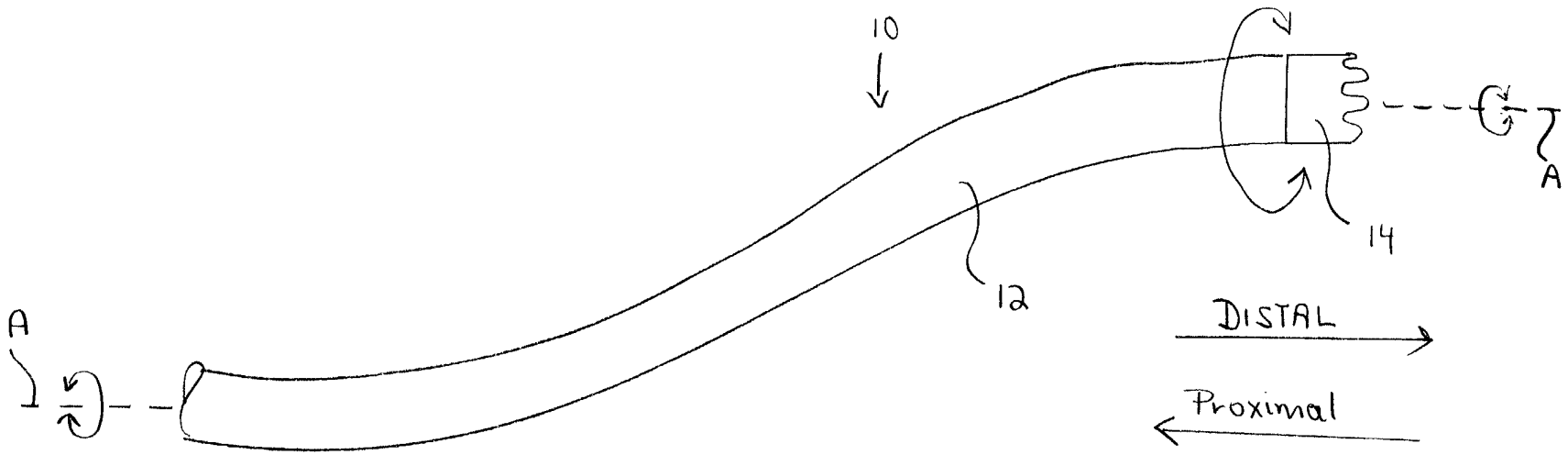


FIG 1

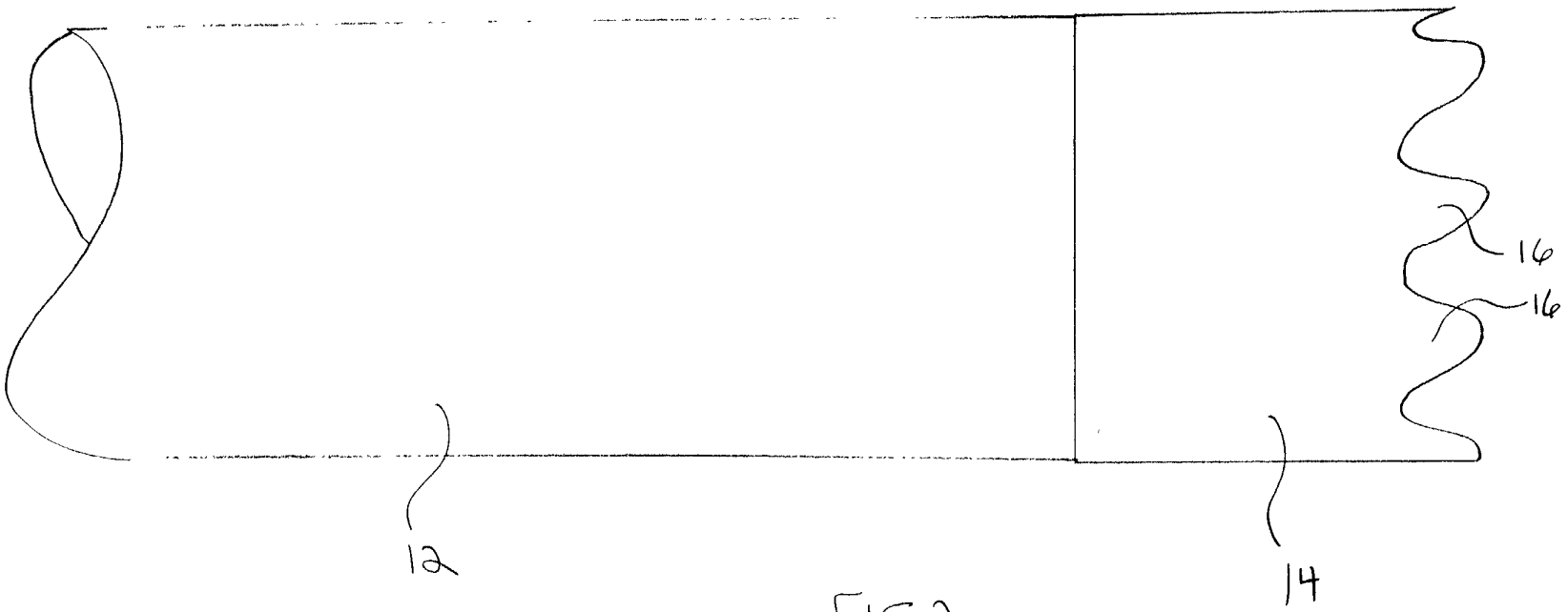


FIG 2

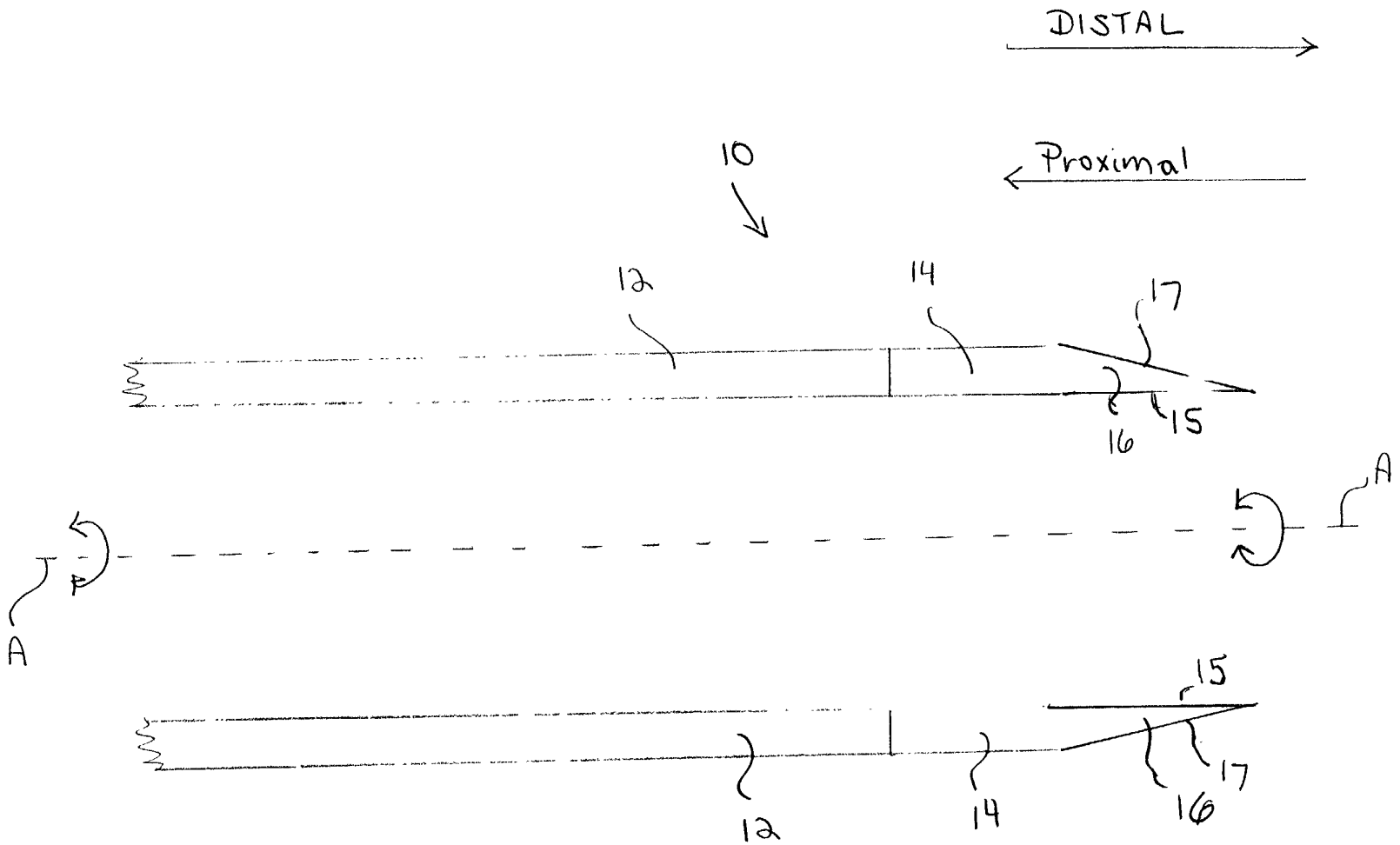


FIG 3

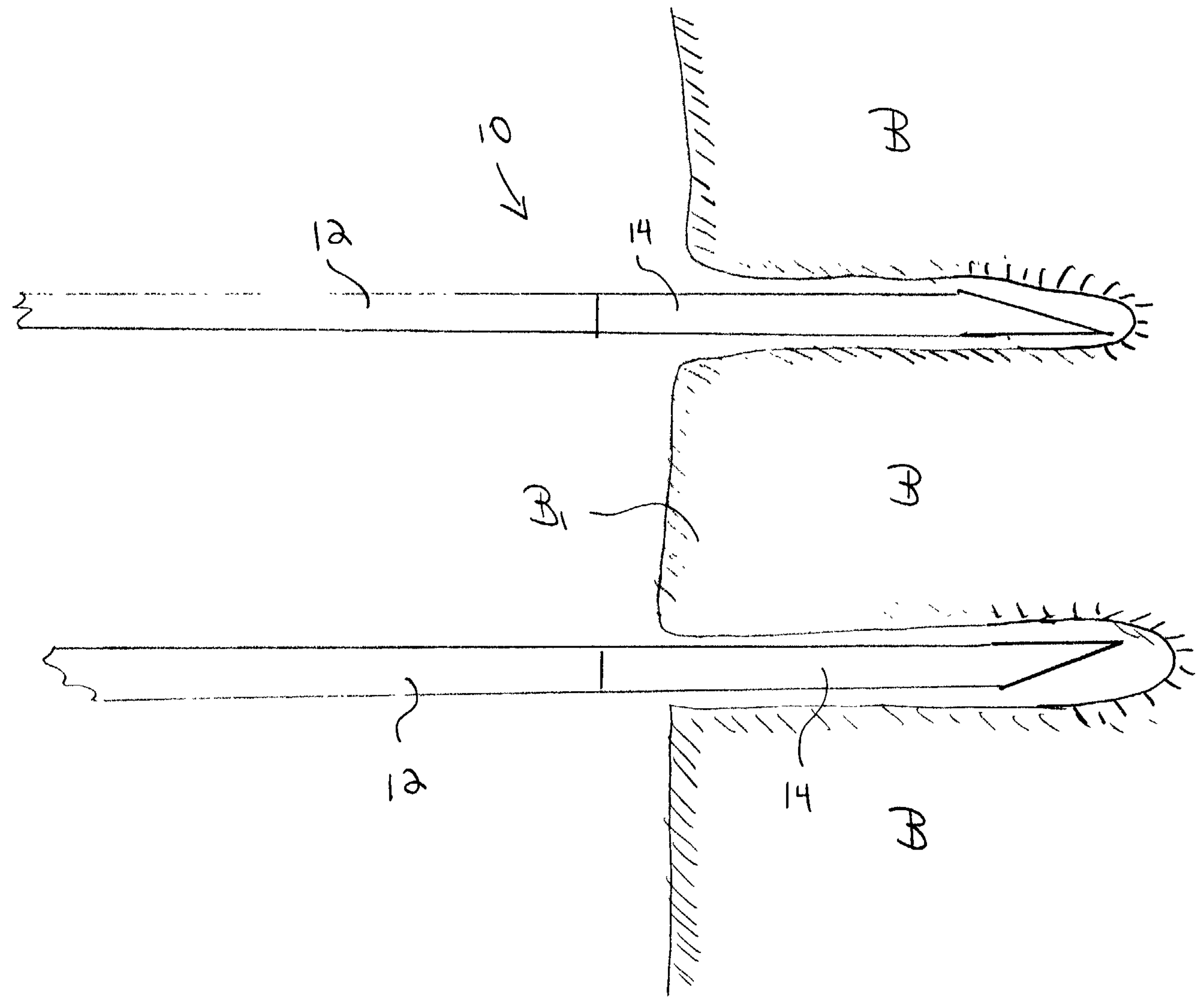


FIG 4

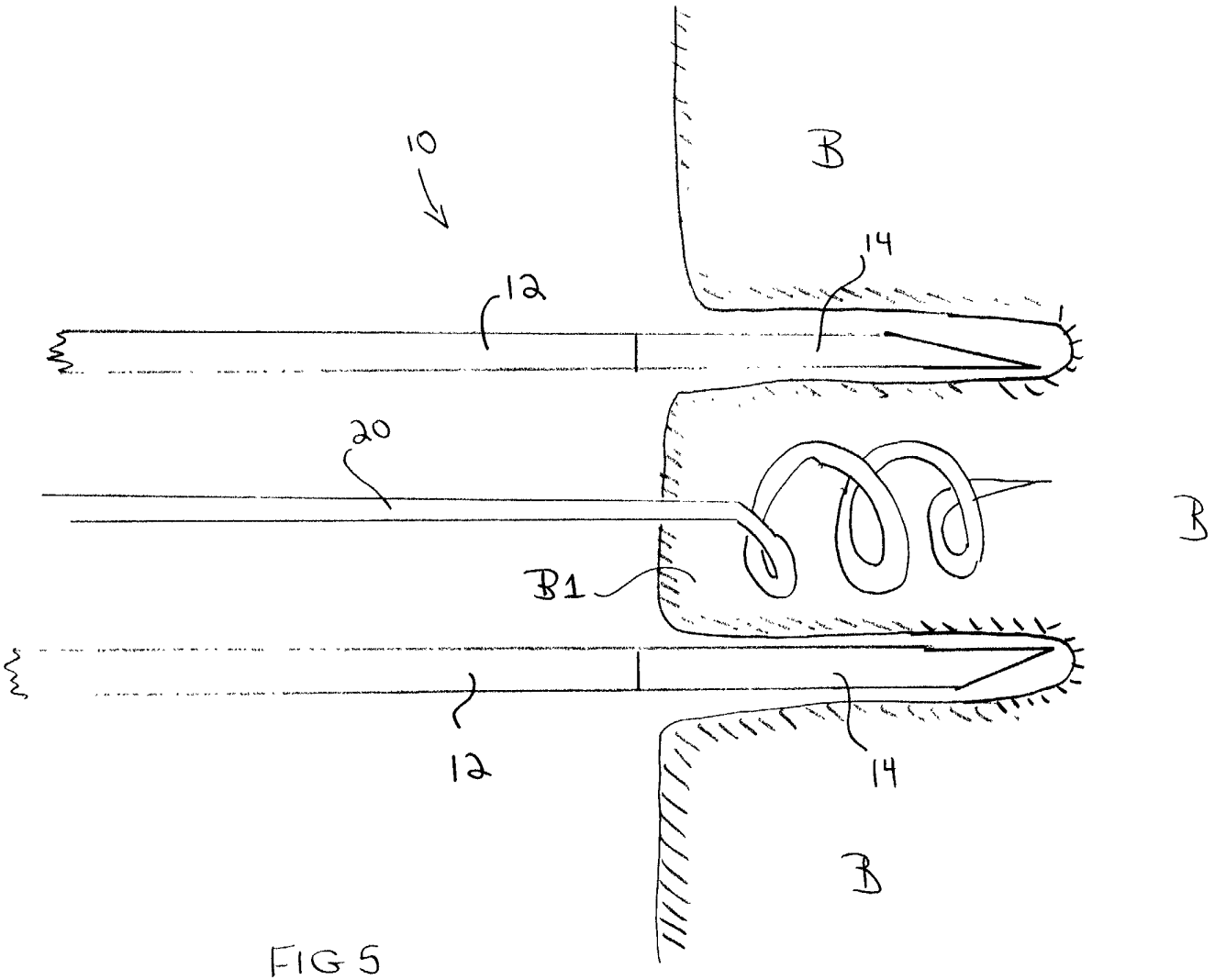


FIG 5

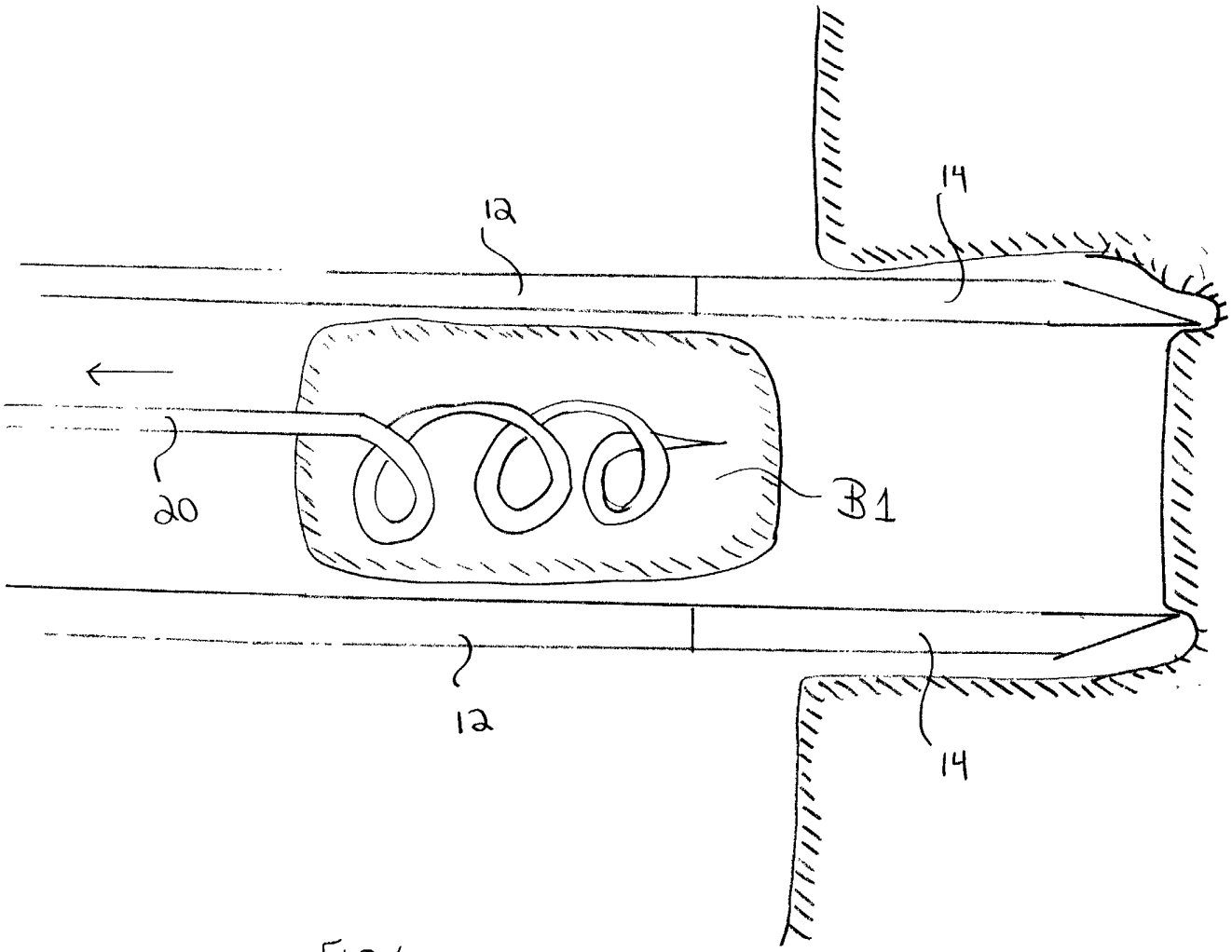


FIG 6

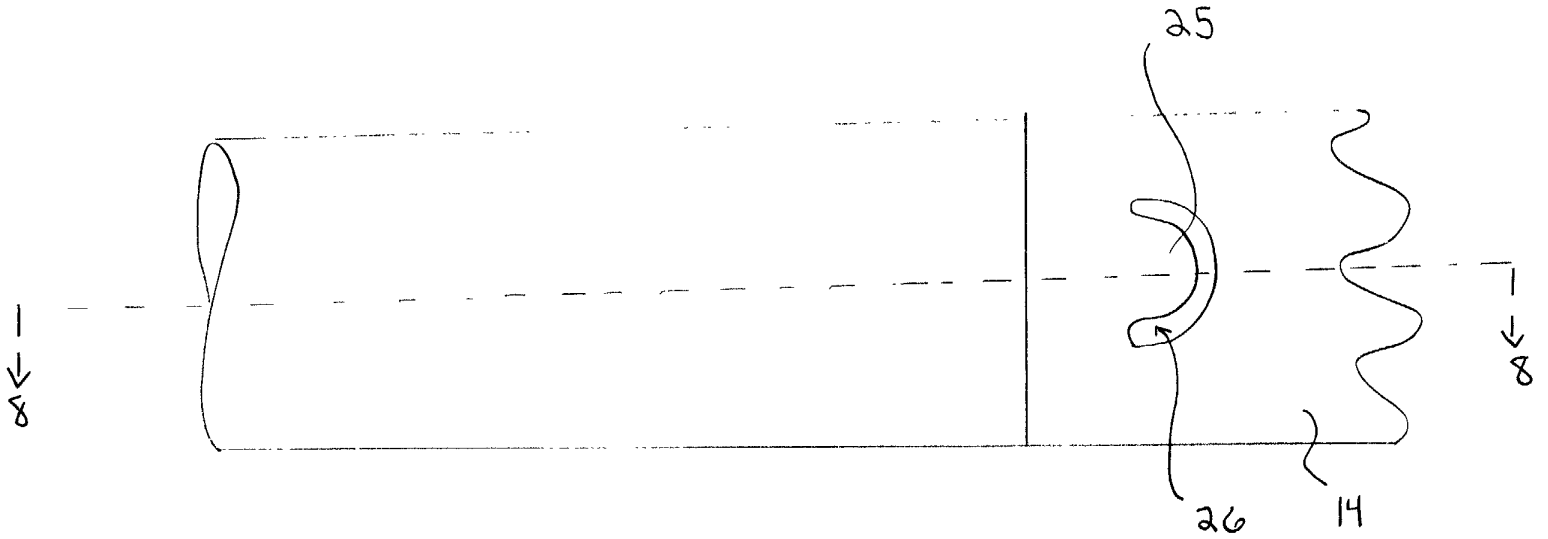


FIG 7

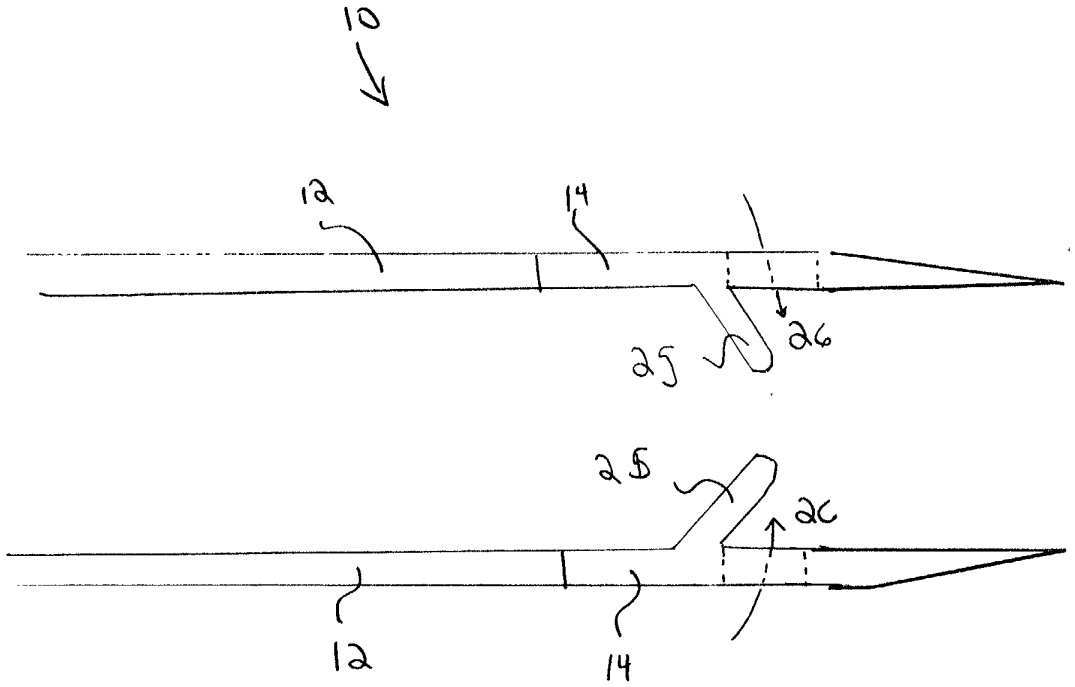
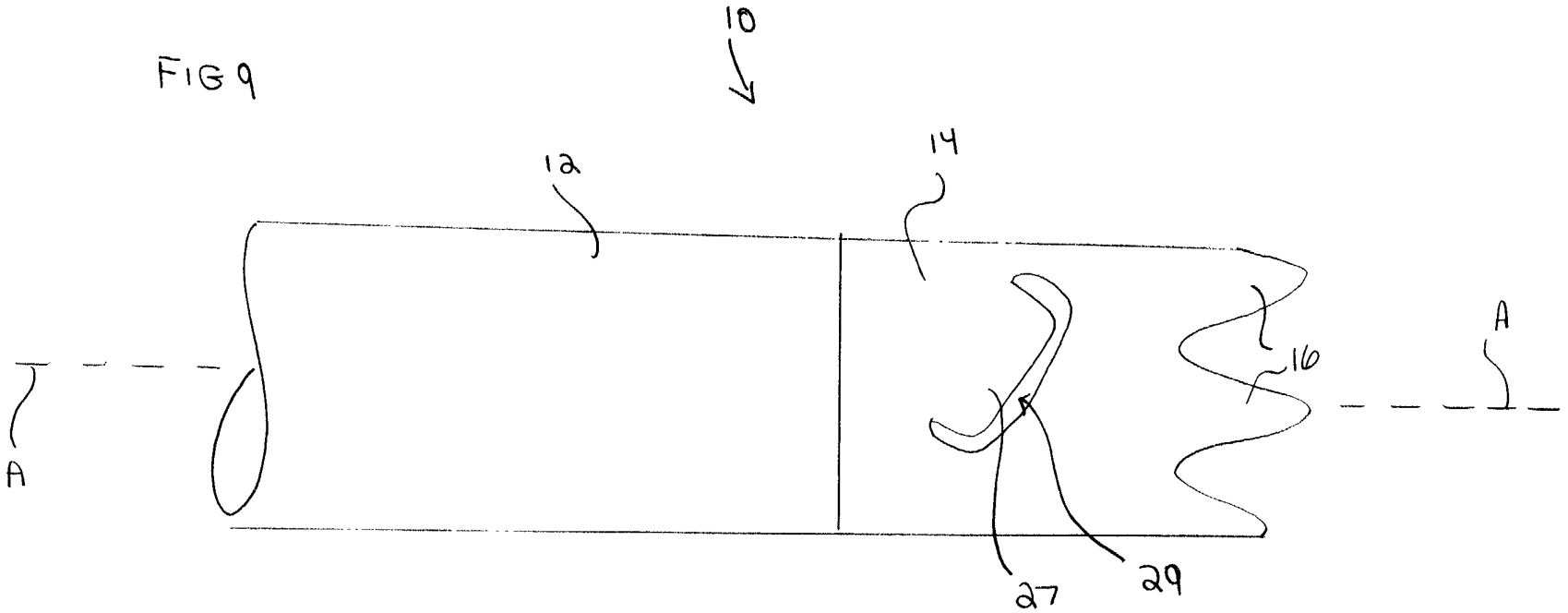


FIG 8

FIG 9



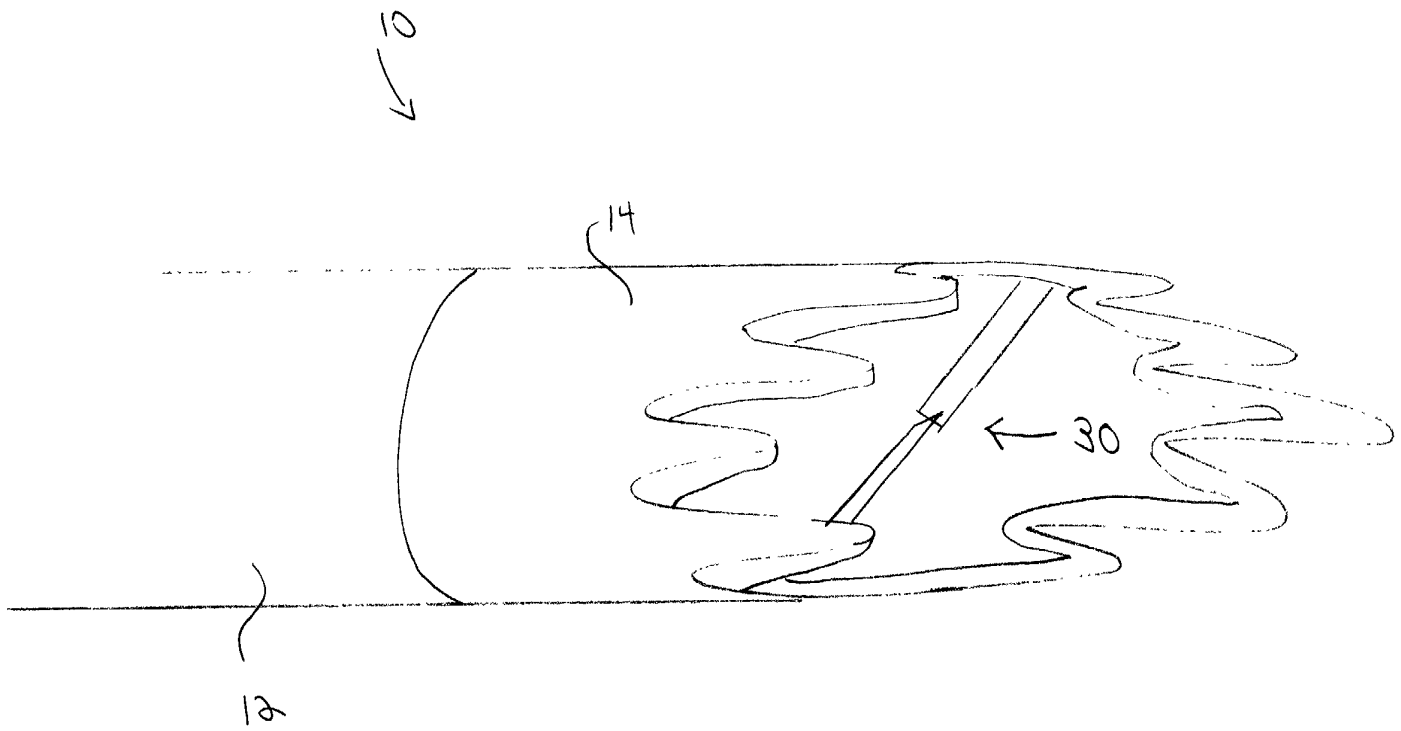


FIG 10

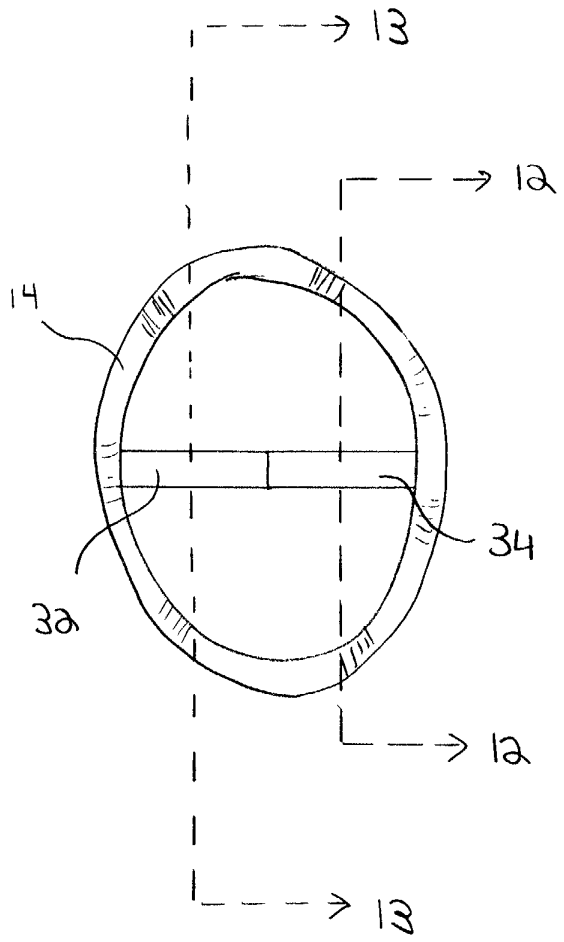


FIG 11

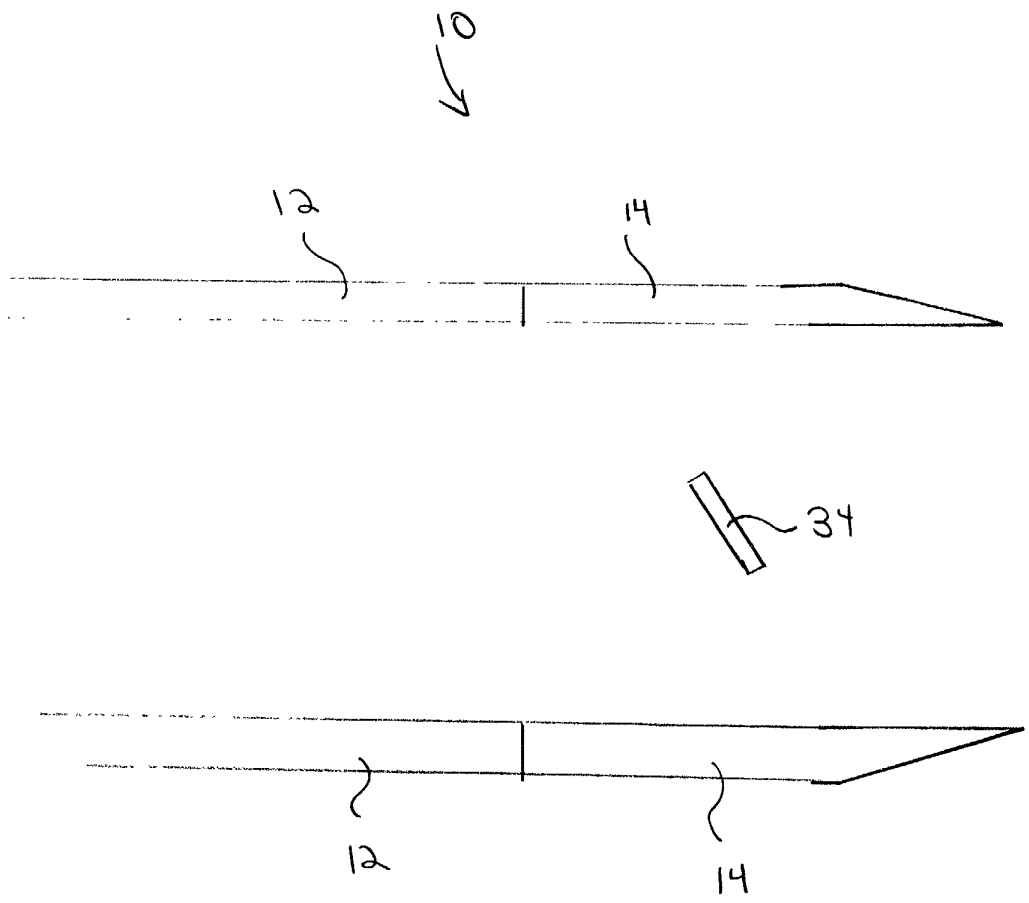


FIG 12

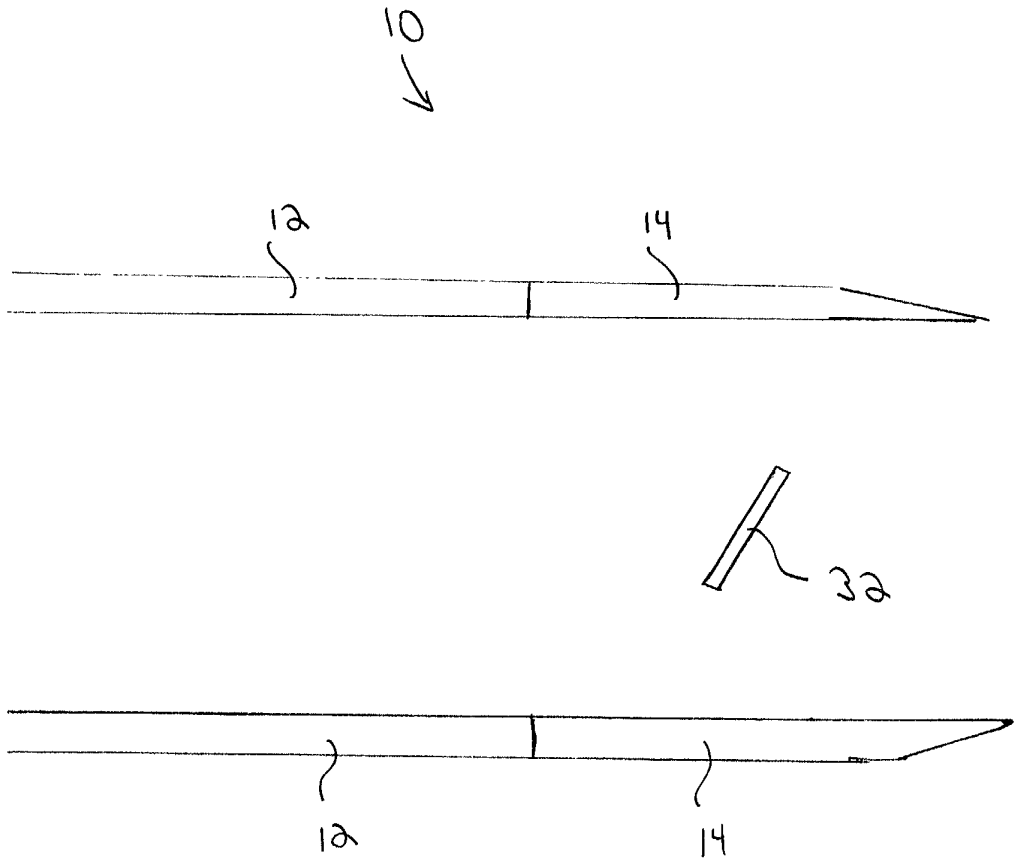


FIG 13

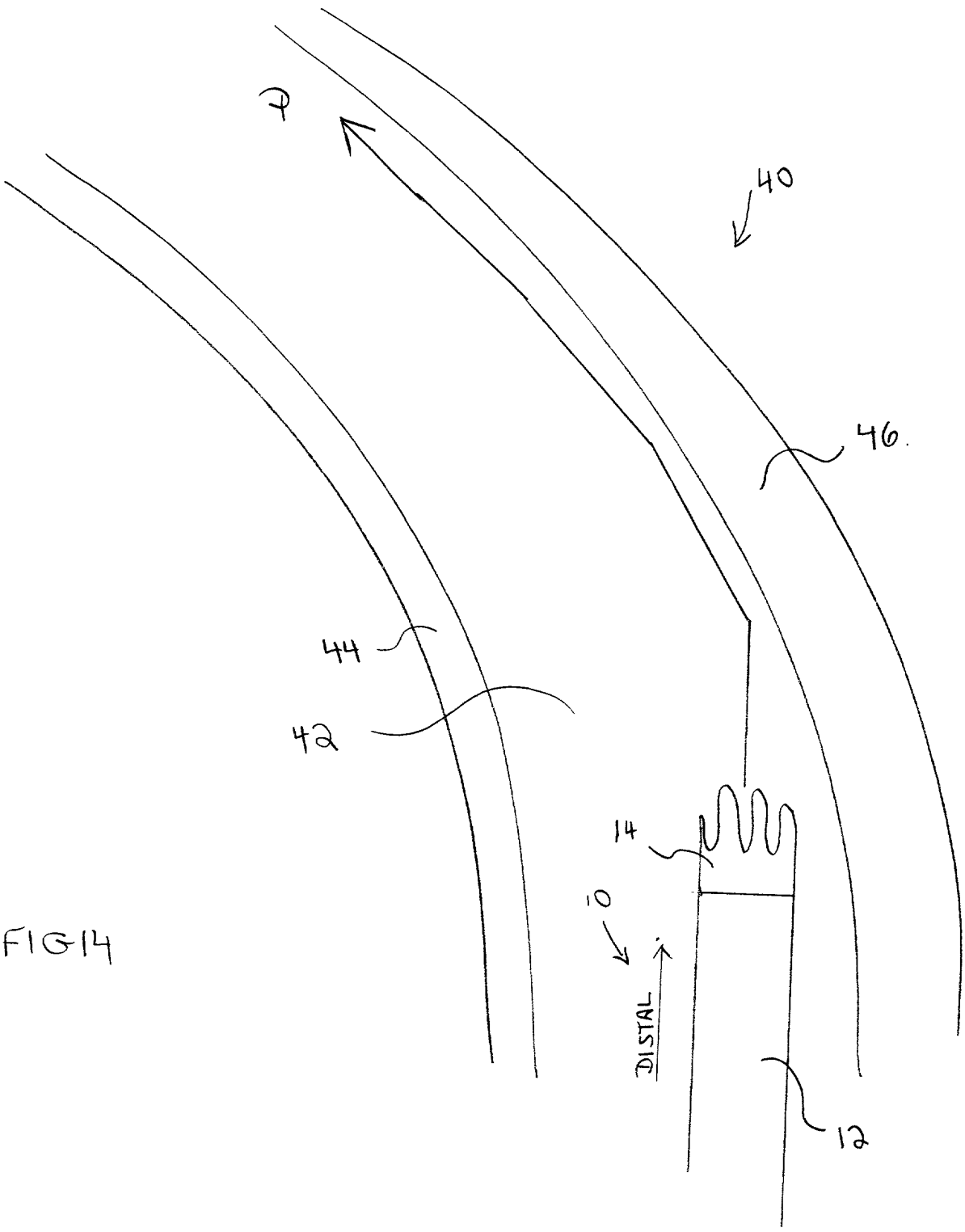


FIG14

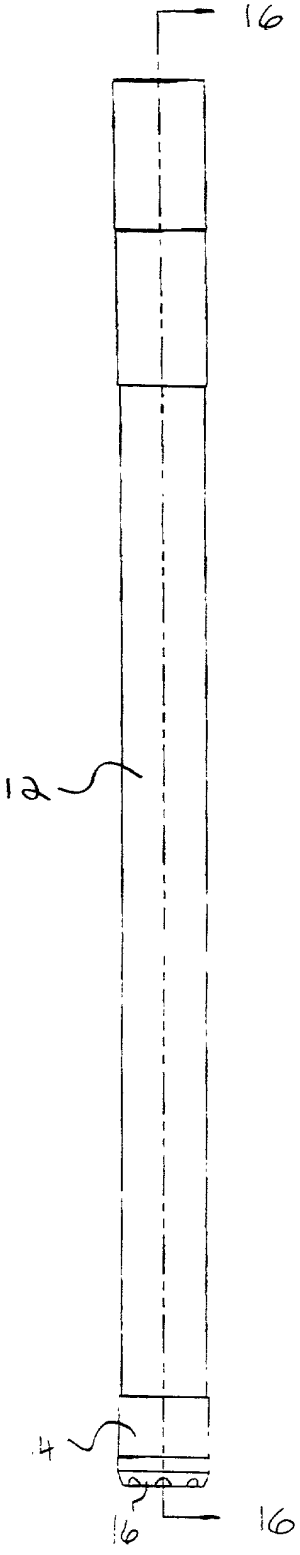


FIG 15

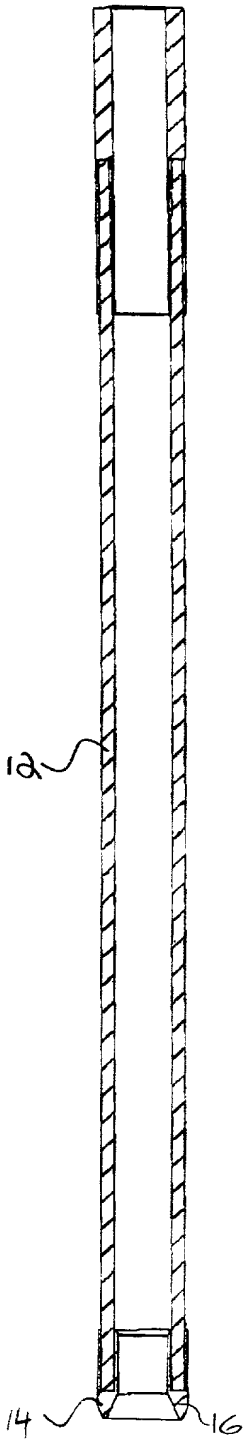


FIG 16

FIG 17

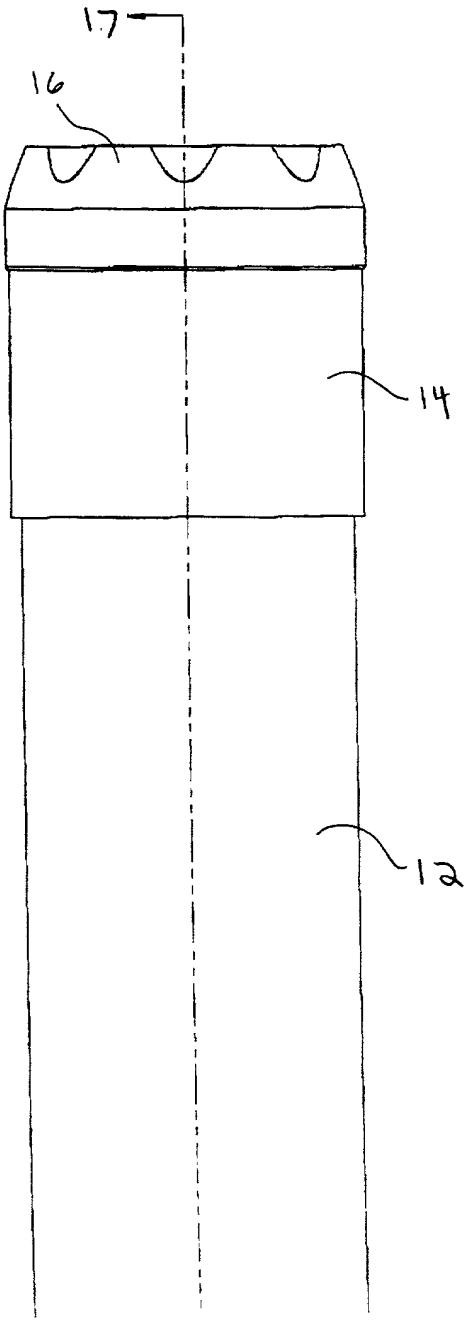
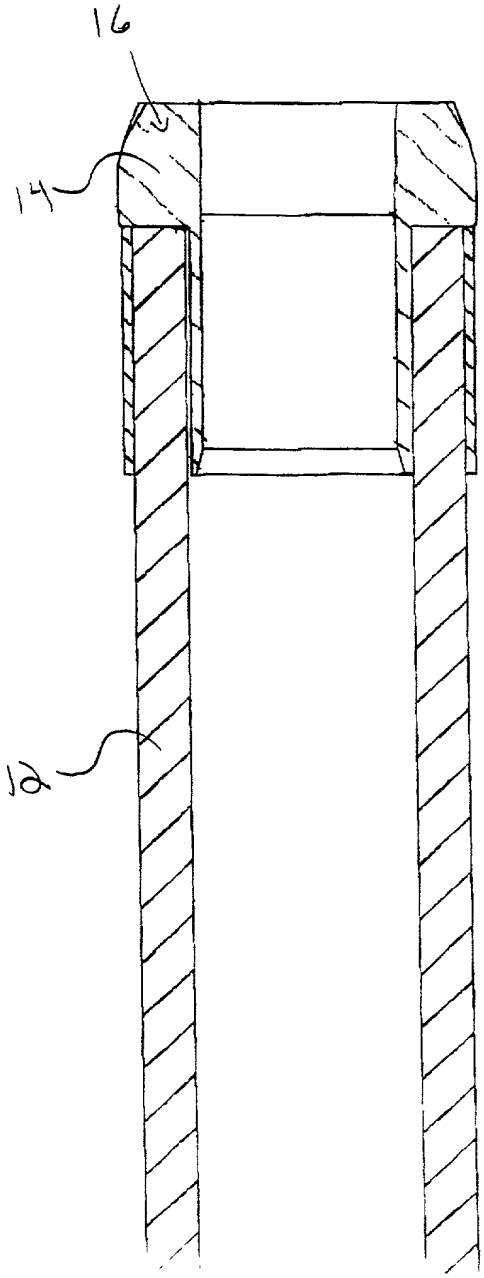


FIG18



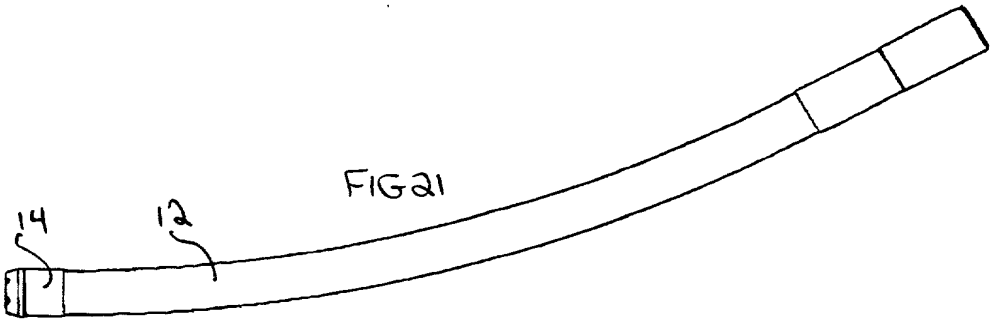


FIG 21

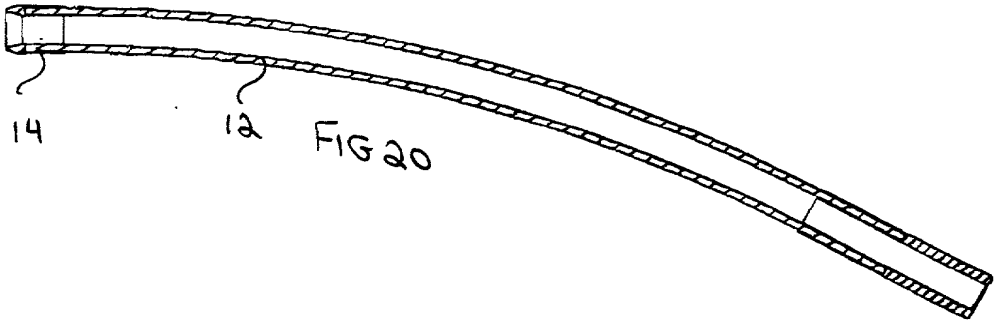


FIG 20

SECTION A-A

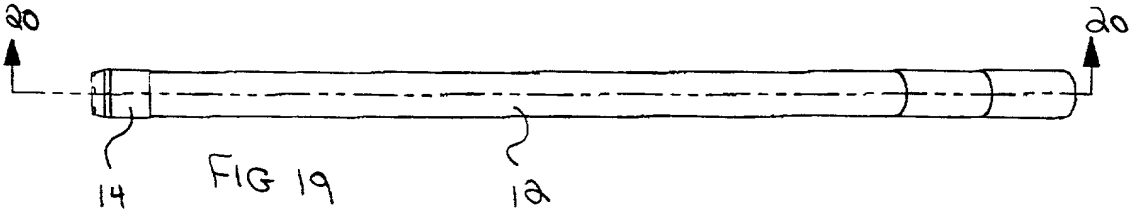


FIG 19

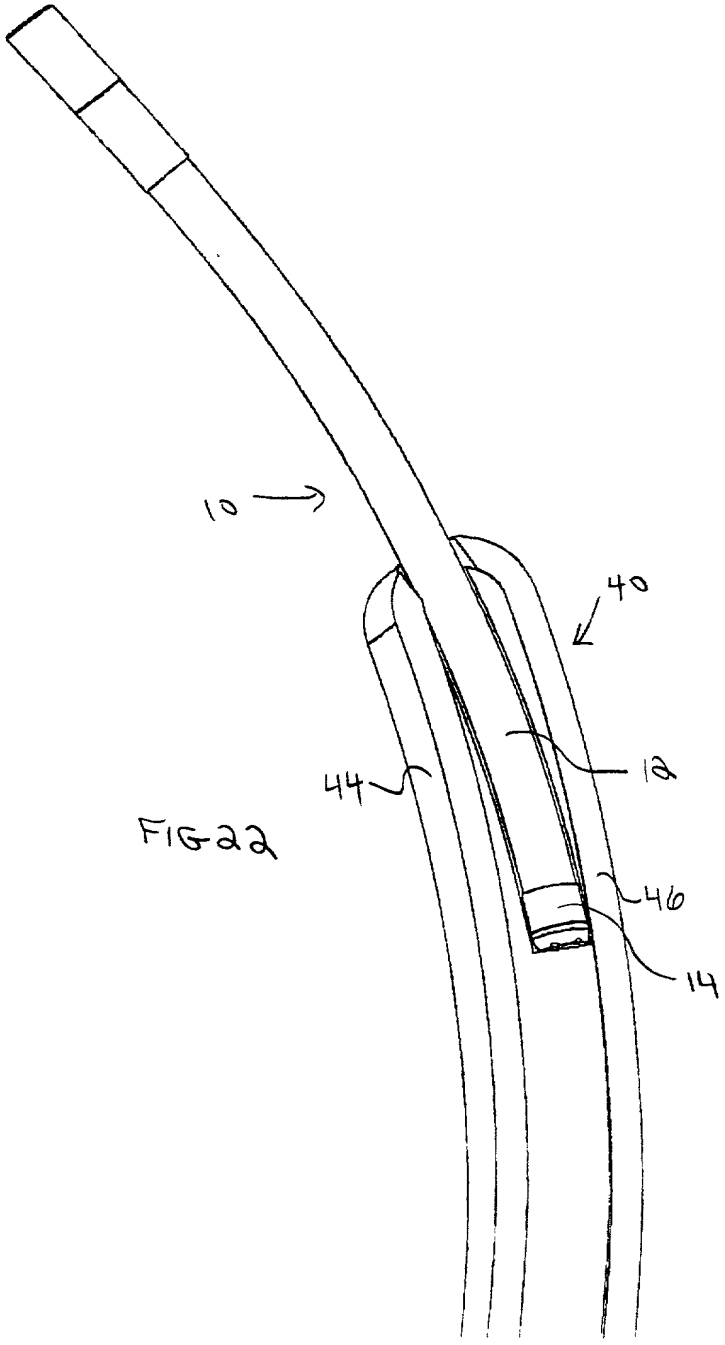


FIG-22

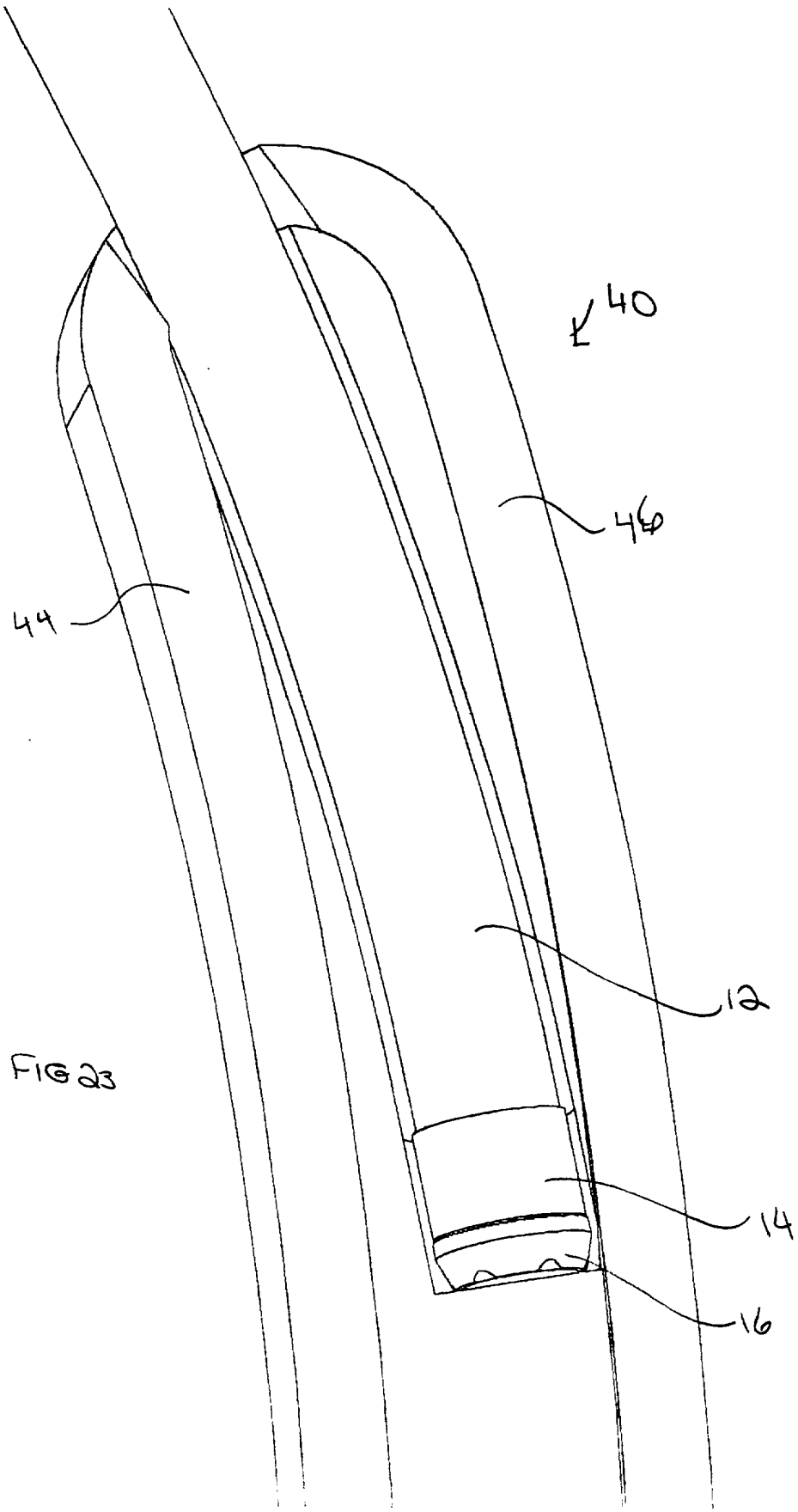


FIG 23

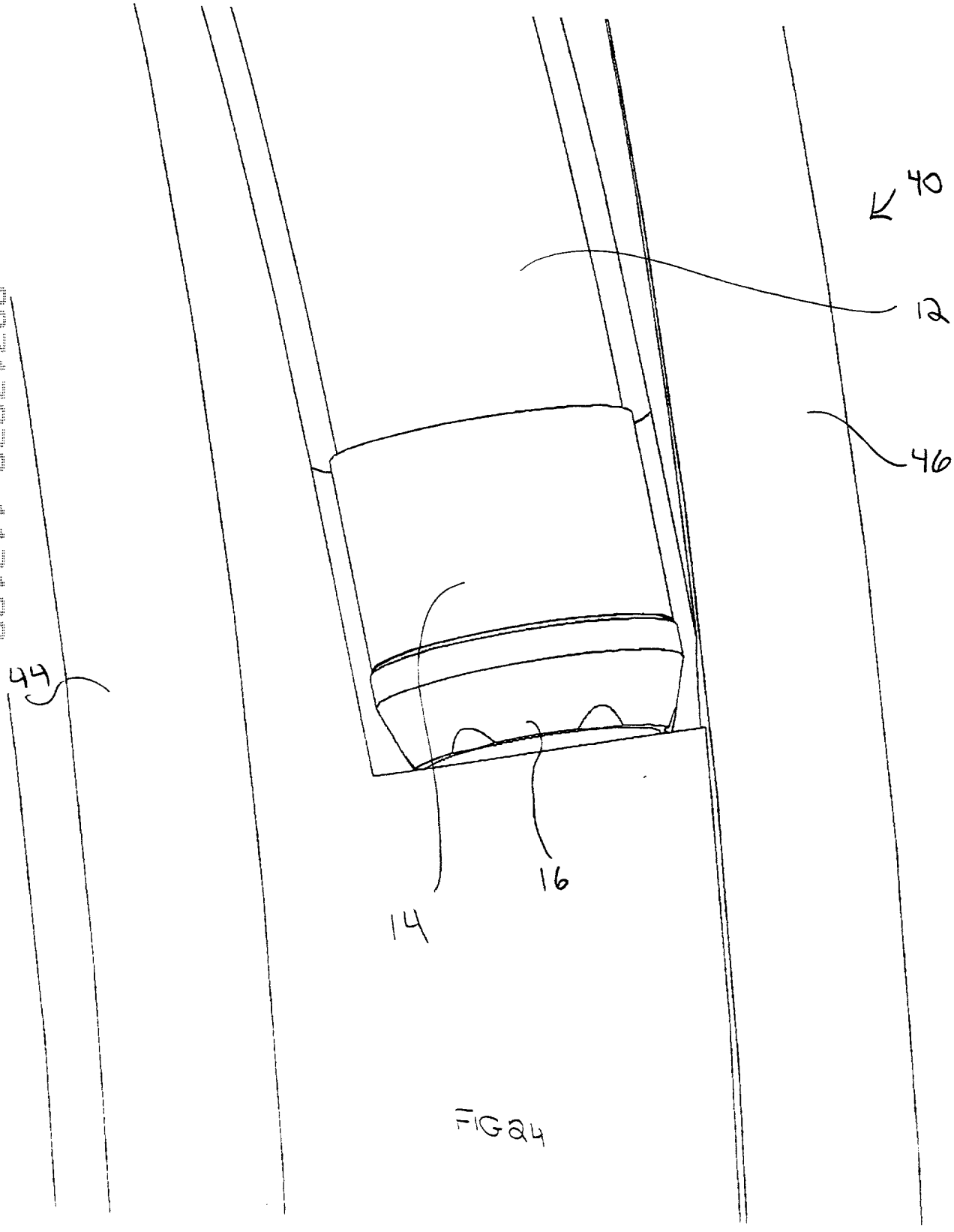


FIG 24

DECLARATION

As a below named inventor, I declare that:

My residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **BONE GRAFT HARVESTER** the specification of which **X** is attached hereto or ____ was filed on _____ as Application No. _____ and was amended on _____ (if applicable).

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56. I claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

Application No.	Filing Date
60/167,192	November 23, 1999

Full Name of Inventor 1:	Last Name: **GILLESPIE**	First Name: **WALTER**	Middle Name or Initial: **D.**	
Residence & Citizenship:	City: **La Mesa**	State/Foreign Country: **California**	Country of Citizenship: **United States**	
Post Office Address:	Post Office Address: **8652 Hayes Street**	City: **La Mesa**	State/Country: **California**	Postal Code **91941**
Full Name of Inventor 2:	Last Name: **MATSUURA**	First Name **DAVID**	Middle Name or Initial: **G.**	
Residence & Citizenship:	City **Escondido**	State/Foreign Country: **California**	Country of Citizenship: **United States**	
Post Office Address:	Post Office Address. **1356 Oak View way**	City. **Escondido**	State/Country: **California**	Postal Code. **92029**
Full Name of Inventor 3:	Last Name: **MARINO**	First Name: **JAMES**	Middle Name or Initial: **F.**	
Residence & Citizenship:	City: **La Jolla**	State/Foreign Country: **California**	Country of Citizenship: **United States**	
Post Office Address:	Post Office Address: **2620 St. Tropez Place**	City: **La Jolla**	State/Country: **California**	Postal Code. **92307**
Full Name of Inventor 4:	Last Name: **STONE**	First Name: **CORBETT**	Middle Name or Initial. **W.**	
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I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1	Signature of Inventor 2	Signature of Inventor 3
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Date	Date	Date

Signature of Inventor 4
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